

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>LTS 2003/003 PCT</b>		FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. <b>PCT/EP2004/003748</b>	International filing date (day/month/year) <b>08.04.2004</b>	Priority date (day/month/year) <b>17.04.2003</b>	
International Patent Classification (IPC) or national classification and IPC			
Applicant <b>LTS LOHMANN THERAPIE-SYSTEME AG</b>			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/003748

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-16 \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- nos. \_\_\_\_\_ as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 1-11 \_\_\_\_\_ received by this Authority on 12.02.2005 with letter of 10.02.2005
- nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- sheets 1/1 \_\_\_\_\_ as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/003748

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. This report makes reference to the following documents:			
D1: WO 01/78678 A (JENKINS DELYTH MYFANWY; KYTE KENNETH EUGENE (US); PHILLIPS JENNIFER E) 25 October 2001			
D2: WO 02/34200 A (LOHMANN THERAPIE SYST LTS; DEGEN ANJA (DE); THEOBALD FRANK (DE) 2 May 2002			
D3: US-B-6 361 7901 (ROLF DAVID ET AL) 26 March 2002			
2. The active substance plaster according to claim 1 and the method for the production thereof according to claim 11 are novel in view of the prior art (PCT Article 33(2)). D1 discloses transparent, or at least translucent, inconspicuous active substance plasters (cf. figure 1; page 32, lines 20-22). Said plasters can optionally contain dyes. D1 does not, however, disclose an active substance plaster containing a combination of dyes and ingredients or active			

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

substances that are dyed or change color over time. D2 (cf. page 4, line 33 to page 5, line 5) and D3 (cf. column 6, lines 26-30) likewise each disclose transparent, inconspicuous active substance plasters. D2 discloses a nicotine plaster. The combination of dyes and ingredients that are dyed or change color over time cannot, however, be derived from the disclosure in D2 or D3.

3. The problem to be solved by the present application was that of providing an active substance plaster that masks the coloring or change of color and is also inconspicuous when worn on the skin (cf. description, page 4, lines 1-8). According to the description (cf. page 6, lines 24-36), the problem is solved by providing a transparent or translucent active substance plaster with one (or more) dye(s) that mask the coloring or change in color of the ingredient without compromising the inconspicuousness of the plaster on the skin. The inconspicuousness of the plaster is described by the functional feature (cf. color brightness value) included in claim 1. This solution to the problem of interest is neither suggested nor rendered obvious by the teaching in D1-D3. Therefore, the claimed subject matter also involves an inventive step pursuant to PCT Article 33(3).

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4. Claims 2-10 are dependent on claim 1 and therefore likewise meet the PCT requirements for novelty and inventive step.
5. The subject matter of claims 1-11 is regarded as industrially applicable and therefore meets the requirements of PCT Article 33(4).